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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,275	10/25/2001	Roger Coleman	PF-0027-1 CON	3250

7590 05/15/2003

INCYTE GENOMICS, INC.
PATENT DEPARTMENT
3160 Porter Drive
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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,275	COLEMAN ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18, 20, 23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. A preliminary amendment was filed which cancelled claims 19, 21, 22, and 24-59. The remaining claims are subject to a restriction requirement as set forth herein.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 17-18, drawn to isolated polypeptides comprising or related to SEQ ID NO: 2, classified in class 530, subclass 350, for example.

II. Claims 1-2 and 17-18, drawn to isolated polypeptides comprising or related to SEQ ID NO: 4, classified in class 530, subclass 350, for example

III. Claims 3-8, 9-10, 12, and 13, drawn to nucleic acids, vectors, host cells, classified in class 536, subclass 23.1, for example.

IV. Claims 3-8, 9-10, 12, and 13, drawn to nucleic acids, vectors, host cells, classified in class 536, subclass 23.1, for example.

V. Claim 11, drawn to an antibody that binds instant SEQ ID NO: 2 or related sequences, classified in class 530, subclass 387.1.

VI. Claim 11, drawn to an antibody that binds SEQ ID NO: 4 or related sequences, classified in class 530, subclass 387.1.

VII. Claims 14-16, drawn to methods for detection of the nucleic acid comprising SEQ ID NO: 1, classified in class 435, subclass 6 or 91.2.

VIII. Claims 14-16, drawn to methods of detecting SEQ ID NO: 3, classified in class 435, subclass 6 or 91.2.

IX. Claim 20, drawn to methods to screen for the effectiveness of an antagonist against SEQ ID NO: 2, classified in class 436, subclass 501.

X. Claim 20, drawn to method of screening a compound for effectiveness as an agonist of SEQ ID NO: 4, classified in class 435, subclass 501.

XI. Claim 23, drawn to a method for screening a compound for effectivness as an antagonist of a SEQ ID NO: 2, classified in class 436, subclass 501.

XII. Claim 23, drawn to a method for screening a compound for effectiveness as an antagonist of SEQ ID NO: 4, classified in class 436, subclass 501.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, III, V, VII, IX, and XI are unrelated to inventions II, IV, VI, VIII, X, and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to produces or methods which utilize products of independent and distinct structure and function. The polypeptide of SEQ ID NO: 2 and the nucleic acid that encodes it is distinct in structure and function from the polypeptide of instant SEQ ID NO: 4 and the nucleic acids that encode it. Each molecule or method using the molecule has a unique structure and function and is therefore independent and distinct.

4. The inventions of groups I, III, and V and the inventions of groups II, IV and VI are patentably distinct because they are drawn to different products having different structures and functions. The polypeptide of Group I or II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The nucleic acid of Group III or IV is composed of nucleotides linked in phospodiester bonds and arranged in space as a

double helix. The antibody of Group V or VI is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of groups I, III, and V and the products of groups II, IV and VI can be used in materially different processes, for example, the DNA of Group III or IV can be used in hybridization assays, the antibody of Group V or VI can be used in immunoassay, the polypeptide of Group I or II can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, III, and V and the inventions of groups II, IV and VI are patentably distinct from each other.

5. The inventions of groups I and V are unrelated to the methods of group VII. The inventions of groups II and VI are unrelated to the methods of group VIII Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not useable together as the products of groups I, V, II, and VI are not used in the hybridization methods of groups VII or VIII.

6. Inventions I is related to inventions IX and XI as product and process of use. Inventions II is related to inventions X and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed ean be used in a materially different proeess of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention I and II can be used in a variety of methods, such as the two reeited in claims 20 and 23 or additionally to raise antibodies or in methods of treatment or to make fusion proteins.

7. Inventions III and VII are related as product and proeess of use. Inventions IV and VIII are related as product and process of use. The inventions ean be shown to be distinet if either or both of the following ean be shown: (1) the proeess for using the produet as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nueleic acid of inventions III and IV ean be used in a variety of methods such as expression assays, nucleie aeid purifieation assays, eloning methods, and to produet polypeptides.

8. Inventions III and V are unrelated to inventions IX and XI. Inventions IV and VI are unrelated to inventions X and XII. Inventions are unrelated if it ean be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not diselosed as being used together as the produets of groups III-VI are not used in the screening methods of groups IX-XII.

9. Inventions VII, IX and XI are unrelated. Inventions VIII, X and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to distinct methods that have different goals, effects and modes of operation.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XII require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

11. A telephone call was made to Diana Hamlet-Cox on 4/24/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet Einsmann Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the

organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.

~~JS~~ Juliet Switzer
AU 1634

May 6, 2003

Gary Jones
Supervisory Patent Examiner
Technology Center 1600